

**Notice of Allowability**

Application No.

10/086,177

Examiner

Bridget E. Bunner

Applicant(s)

TUDAN ET AL.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response of 24 July 2007.
2. ☒ The allowed claim(s) is/are 33-38 (renumbered as claims 1, 2, 5, 3, 4, and 6, respectively).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient..
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 7/24/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on 24 July 2004 has been considered by the Examiner.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Boyer on 08 June 2007:

In claim 33, line 5 : After the phrase "1-14" insert therefore --of SEQ ID NO: 208--

In claim 33, line 8: Delete "comprises 4 natural amino acids" and insert therefore --consists of 4 glycines --

In claim 35, line 1: Delete "A composition of" and insert therefore --A composition comprising a CXC chemokine receptor 4 (CXCR4) agonist wherein the agonist comprises--

Claim 36. ~~An amino acid sequence having at least 95% homology to the agonist of claim 33 and having the function of binding to a CXCR4 receptor.~~ A variant of the CXCR4 agonist of claim 33, wherein said variant differs from said agonist by the following:

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- a) the variant has an N-terminal 14 amino acids that is at least 95% identical to amino acids 1-14 of SEQ ID NO: 208; or
- b) the variant has a C-terminal 13 amino acids that is at least 95% identical to amino acids 19-31 of SEQ ID NO: 208.

In claim 37, line 1: Delete "amino acid sequence" and insert therefore --CXCR4 agonist variant--

38. ~~An amino acid sequence having at least 95% homology to the composition of claim 35 and having the function of binding to a CXCR4 receptor.~~ A variant of the CXCR4 agonist of claim 35, wherein said variant differs from said agonist by the following:

- a) the variant has an N-terminal 14 amino acids that is at least 95% identical to amino acids 1-14 of SEQ ID NO: 208; or
- b) the variant has a C-terminal 13 amino acids that is at least 95% identical to amino acids 19-31 of SEQ ID NO: 208.

#### EXAMINER'S COMMENT

It is noted that support for the new claim language recited claims 36 and 38 flows from the specification at page 17, lines 7-20. Additionally, amino acids 1-14 of SEQ ID NO: 208 correspond to amino acids 1-14 of human stromal cell derived factor-1 (SDF-1) (see specification at page 44, lines 1-9; page 47, lines 19-23). Amino acids 19-31 of SEQ ID NO: 208 correspond to amino acids 55-67 of SDF-1 (see page 47, lines 19-23).

*Reasons for Allowance*

1. The following is an examiner's statement of reasons for allowance:

The CXC chemokine receptor 4 agonists recited in the claims are novel and nonobvious. The claims of the instant application are free of prior art because the generation of the claimed stromal cell derived factor-1 (SDF-1) peptide agonists has not been disclosed or studied in the prior art. The specification of the instant application discloses that SDF-1(1-14)-(G)<sub>4</sub>-SDF-1(55-67)-K20/E24-cyclic amide (also referred to as CTCE0021; SEQ ID NOs: 57, 208) has numerous activities, such as (but not limited to) inhibition of cell cycling in human positive erythroid and primitive granulocyte cells (pg 52, lines 1-5; Table 2), repression of the proliferation of clonogenic erythroid and granulopoietic progenitors in an *in vitro* LTC-IC assay (pg 55, lines 1-21; Table 4; Figure 7), significant amelioration of the decrease in white blood cell count caused by Ara-C (pg 52, lines 20-25; Figure 1), inhibition of the cytotoxic effects of Ara-C, and a prolonged higher level of leukocytes *in vivo* as compared to control (pg 59, lines 1-7; Figures 10-11). The specification of the instant application also discloses that SDF-1(1-14)-(G)<sub>4</sub>-SDF-1(55-67)-E24/K28-cyclic amide (also referred to as CTCE0022; SEQ ID NO: 132) has numerous activities, such as (but not limited to) binding of the CXCR4 receptor with high affinity and mediation of intracellular Ca<sup>2+</sup> mobilization (pages 53-54; Examples 4-5). Thus, the specification meets 35 U.S.C. 112, first paragraph, requirements because it contains an adequate written description of the invention that enables one of ordinary skill in the art to make and use the invention. The specification also sets forth the best mode to carry out the invention. The claims also meet 35 U.S.C. 112, second paragraph, requirements because the claims point out and distinctly claim the invention.

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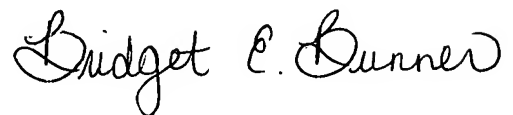
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
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30 August 2007



BRIDGET E. BUNNER  
PRIMARY EXAMINER